

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

UNITED STATES OF AMERICA, et al.,
ex rel. CALEB HERNANDEZ and JASON
WHALEY, Relators

Plaintiffs,

v.

TEAM HEALTH HOLDINGS INC., et al.

Defendants.

CASE No. 2:16-cv-00432-JRG

**DEFENDANTS' SUPPLEMENTAL MEMORANDUM IN FURTHER SUPPORT OF
THEIR MOTION TO EXCLUDE THE OPINION TESTIMONY OF
RELATORS' DESIGNATED EXPERT BRUCE WAPEN**

Defendants Team Health Holdings, Inc., Team Finance, L.L.C., Team Health, Inc., AmeriTeam Services, L.L.C., HCFS Health Care Financial Services, L.L.C., and Quantum Plus, L.L.C. (collectively, "Defendants") respectfully file this Supplemental Memorandum in Further Support of Their Motion to Exclude the Opinion Testimony of Relators' Designated Expert Bruce Wapen to address additional grounds for the exclusion of Wapen's opinions and analyses in light of information revealed in Wapen's November 6, 2020 deposition.

Pursuant to Federal Rule of Evidence 702, Defendants respectfully request that Wapen be prevented from offering any opinions or testimony at trial because his proffered opinions depend entirely on informal, non-binding, sub-regulatory guidance in violation of *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1816 (2019), and in violation of Department of Justice and CMS policy prohibiting enforcement actions based solely on sub-regulatory guidance. Defendants further

request that this Court exclude any opinions, testimony, or analyses by Relators' other experts—Kristen Folding and Dr. Douglas Steinley—premised on Wapen's improper analyses.

I. RELEVANT FACTUAL BACKGROUND

Relators designated Wapen as an expert witness on August 10, 2020 and contemporaneously served a copy of his expert report. *See* Ex. B, Wapen Expert Rep.¹ They designated Wapen to evaluate Defendants' medical records and opine regarding Defendants' critical care documentation, coding, and billing. *See* Ex. B, at 2; *see also* Ex. C, Wapen Supplemental Rep. On September 17, 2020, Defendants filed a Motion to Exclude Wapen's expert testimony.² Defendants deposed Wapen almost two months later on November 6, 2020. *See* Ex. A, Wapen Dep. Tr.

Additional grounds for the exclusion of Wapen's anticipated testimony surfaced during his November 6 deposition. Specifically, for the first time, Wapen revealed that all of his opinions—both his opinions relating to [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. *See, e.g.*, Ex. A, at 177:16–179:6, 189:9–191:13. Although his expert report identified the Manual as a source he consulted, it was not until the deposition that Wapen expressly stated that the Manual was in fact [REDACTED].

¹ *See also* Dkt. No. 151, at 3; Dkt. No. 154.

² *See* Dkt. No. 165.

II. THE COURT SHOULD EXCLUDE WAPEN’S OPINIONS AND TESTIMONY BECAUSE THEY RELY EXCLUSIVELY ON NON-BINDING, SUB-REGULATORY GUIDANCE.

Wapen’s opinions and testimony should be excluded because they violate the Supreme Court’s decision in *Azar v. Allina Health Services*, which established that False Claims Act (“FCA”) violations must implicate binding, substantive legal standards. *See* 139 S. Ct. at 1816. Wapen’s deposition revealed that he relied solely on critical care guidelines set out in the Manual—a non-binding, sub-regulatory source—when conducting his analysis and forming his opinions, rendering them unreliable and legally improper.

The Supreme Court’s decision in *Allina* established that the Medicare statute’s notice and comment requirement renders sub-regulatory guidance—such as the guidelines in the Manual, which are not subject to notice and comment—invalid when it establishes or changes a substantive legal standard, which includes performing a “gap-filling” function such as is the case with the Manual provisions relied upon by Wapen. *Id.* at 1817 (“[W]hen the government establishes or changes an avowedly ‘gap’-filling policy, it can’t evade its notice-and-comment obligations under § 1395hh(a)(2)[.]”); *Polansky v. Executive Health Res., Inc.*, 422 F. Supp. 3d 916, 936 (E.D. Pa. 2019) (“Relator cannot justify CMS’s failure to provide notice and comment for the 24-hour policy by characterizing it as mere guidance on a preexisting standard when the policy, in substance, is a gap-filling exercise prompted by the ambiguity of the prior policy.”); *see also* 42 U.S.C. § 1395hh(a)(2) (“No rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation[.]”). Wapen’s testimony makes clear that he relies [REDACTED] to determine

which medical records purportedly [REDACTED] (and therefore purportedly false claims under the FCA). *See infra* pp. 4–6.

Furthermore, sub-regulatory authorities that violate the Medicare Act cannot serve as the basis for FCA liability. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995–96 (2016) (explaining that FCA liability attaches when a claim submitted to the Government “fails to disclose the defendant’s noncompliance with a statutory, regulatory, or contractual requirement”); *see also* 28 C.F.R. § 50.26(a)(3) (“An agency guidance document may not be used as a substitute for regulation and may not be used to impose new standards of conduct on persons outside the Executive Branch except as expressly authorized by law or as expressly incorporated into a contract.”). Recent directives from the Department of Justice (“DOJ”) confirm this: “[T]o the extent that [CMS manuals] and similar guidance set forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because under *Allina*, it was not validly issued.” Department of Health and Human Services – Office of the Inspector General, Kelly M. Cleary & Brenna E. Jenny, Memorandum Regarding Impact of *Allina* on Medicare Payment Rules (Oct. 31, 2019); *see also* Dkt. No. 165, at 3–6 (discussing various DOJ pronouncements against the use of its enforcement authority to convert sub-regulatory guidance documents into binding rules).

As the current U.S. Attorney for the Eastern District of Texas, Stephen Cox, has commented, “in a False Claims Act case, if a company does not comply with some agency’s guidance document that interprets some statute or regulation, our attorneys are not going to treat that as itself establishing a violation of law.” *See* DOJ News, *Deputy Associate Attorney General Stephen Cox Provides Keynote Remarks at the 2020 Advanced Forum on False Claims and Qui Tam Enforcement* (Jan. 27, 2020), <https://www.justice.gov/opa/speech/deputy-associate-attorney->

general-stephen-cox-provides-keynote-remarks-2020-advanced. As a result, any purportedly false statement that relies exclusively on sub-regulatory guidance cannot be “material” within the meaning of the False Claims Act as a matter of law. *Escobar*, 136 S. Ct. at 2003 (“Materiality . . . cannot be found where noncompliance is minor or insubstantial.”).

In concluding that certain claims submitted by Defendants should be [REDACTED] [REDACTED]—and, therefore, that the claims were “false” within the meaning of the FCA—Wapen’s opinions and testimony treat noncompliance with an agency guidance document as “itself establishing a violation of law.” *See* DOJ News, *supra* p. 4. Indeed, Wapen testified clearly that [REDACTED] in forming his opinions related to the standards for providing and documenting critical care services:

[REDACTED]

Q Now, outside of Chapter 12, Section 30.6.[1]2 of

[REDACTED]

Ex. A, at 177:16–21, 178:7–179:6. Wapen further testified that he relied [REDACTED]

[REDACTED] rather than any statute or regulation, to opine whether [REDACTED]

Q (By Ms. Grant) Did you rely on -- on the Medicare Claims Processing Manual for your determination

Ex. A, at 189:21–190:1, 190:8–191:13. Wapen also confirmed that he was not offering any opinions that claims submitted by Defendants were false separate from his critiques of Defendants’ purported failure to meet the documentation standards, which are *set forth in the sub-regulatory Manual*:

[REDACTED]

Ex. A, at 84:21–85:15; *see also id.* at 177:16–21, 178:7–179:6 (citing [REDACTED]

[REDACTED]

As this testimony makes clear, Wapen’s opinions are based entirely on informal, non-binding, sub-regulatory guidance, and thus they are neither probative nor reliable in conveying any meaningful information to the jury. To conclude otherwise would conflict with the Supreme Court’s holding in *Allina*, as well as with DOJ and CMS policy.

III. CONCLUSION

For these reasons and those set forth in Defendants’ original Motion to Exclude (Dkt. No. 165) and reply brief (Dkt. No. 215), Defendants respectfully request that the Court enter an order

excluding the opinion testimony of Wapen in its entirety, as well as any testimony of Folding and Steinley that depends on Wapen's unsupported, unreliable, and legally flawed opinions or analyses.

Dated: December 1, 2020

Respectfully submitted,

By: /s/Eric H. Findlay

Eric H. Findlay

Roger Brian Craft

Findlay Craft, P.C.

102 N College Avenue

Suite 900

Tyler, TX 75702

Tel: (903) 534-1100

Fax: (903) 534-1137

efindlay@findlaycraft.com

bcraft@findlaycraft.com

Thomas M. Melsheimer (*Lead Attorney*)

Michael Brett Johnson

Winston & Strawn LLP

2121 N. Pearl Street

Suite 900

Dallas, TX 75201

214-453-6500

Fax: 214-453-6400

tmelsheimer@winston.com

mbjohnson@winston.com

Paula Weems Hinton

Robine Kirsty Morrison Grant

Winston & Strawn LLP

800 Capitol St., 24th Floor

Houston, TX 77002

Tel: (713) 651-2600

Fax: (713) 651-2700

phinton@winston.com

rgrant@winston.com

George B. Breen

EPSTEIN BECKER & GREEN, P.C.

1227 25th Street, NW

Washington, DC 20037

Tel: (202) 861-1823

Fax: (202) 861-3523
GBreen@ebglaw.com

Christopher Farella
EPSTEIN BECKER & GREEN, P.C.
One Gateway Center
Newark, NJ 07102
Tel: (973) 639-8541
Fax: (973) 639-8739
cfarella@ebglaw.com

*Counsel for Defendants Team Health Holdings
Inc., Team Finance, L.L.C., Team Health Inc.,
AmeriTeam Services, L.L.C., HCFS Health Care
Financial Services, L.L.C., and Quantum Plus,
L.L.C.*

CERTIFICATE OF AUTHORIZATION TO FILE UNDER SEAL

I certify that Defendants' Supplemental Memorandum is authorized to be filed under seal
by the Unopposed Motion for Leave to Seal, Dkt. No. 335, filed in this matter.

/s/ Eric H. Findlay
Eric H. Findlay

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2020, I electronically filed the foregoing document
with the Clerk of Court using the CM/ECF system, which will automatically send e-mail
notification of such filing to all counsel of record.

/s/ Eric H. Findlay
Eric H. Findlay